

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

JODI ROUVIERE and	)	
ANDRE ROUVIERE,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 1:18-cv-04814-LJL-SDA
	)	
DEPUY ORTHOPAEDICS, INC. n/k/a	)	
MEDICAL DEVICE BUSINESS	)	
SERVICES, INC. and HOWMEDICA	)	
OSTEONICS CORPORATION	)	
d/b/a STRYKER ORTHOPAEDICS,	)	
	)	
Defendants.	)	

**DECLARATION OF SOL BOBST, PhD DABT**

I, Sol Bobst, PhD DABT, hereby affirm and declare under penalties of perjury that the below facts and claims are true and correct:

1. I am over the age of 18 and a citizen of the United States. I currently reside in Texas.
2. I am a toxicologist with more than 17 years of professional experience, and I am board certified by the American Board of Toxicology. I am an Adjunct Assistant Professor in the Department of Pharmacology and Toxicology at the Boonshoft School of Medicine, of Wright State University in Dayton, Ohio, and an Adjunct Assistant Professor in the Department of Pharmacology and Toxicology at the University of Texas Medical Branch (UTMB) in Galveston, Texas. I received my PhD in Toxicology from the University of Texas Health Science Center Houston / MD Anderson Cancer Center in December, 2003. I have published a risk assessment paper and I have edited two published books on toxicological risk assessment. I have

also lectured and taught graduate level courses on toxicological risk assessment at Wright State University and UTMB.

3. On or about September 18, 2020, I was asked to provide expert opinions in the case of Rouviere vs Depuy et al. I have evaluated the medical records and other documents as they relate to providing interpretations and providing scientific opinions relevant to this case. I have also reviewed numerous publications as listed in the reference section. In forming my opinions, I have used generally accepted methods, Including Weight of Evidence methodologies, that I apply in all my work as a toxicologist that is related to assessing scientific evidence in civil and criminal cases involving intoxication opinions. These include the rules as they are described in the Federal Rules of Scientific Evidence (Federal Rules 2014).

4.. On September 21, 2020, I submitted my written report and opinion after evaluating the Jodi Medical Record Complete 2019, OP Reports 2012, 2016, 2017, Product Metallurgy Metallosis in Imaging Surgery Records, ASIA foreign body, Blood Pathology Tissue Pathology, Gannon Pathology Report, and reviewing relevant medical literature for this case noted in my written report.

5. I determined that facts: Mrs. Rouviere underwent hip replacement and hip replacement removal surgeries in 2012, 2016 and 2017. Since her first surgery, she has experienced neurological and immunological symptoms. Pathology and blood test reports have indicated the presence of metal debris in tissue surrounding the hip, and elevated metal ions in her blood. Exposure to metals from medical device degradation is likely to have begun in 2012 following her first surgery. This exposure would create an increased risk for neurological and immune responses, based on the known impact of metal debris and the well-established patterns of toxicity linked to the metal ions linked to these implants (e.g. Cobalt, Chromium, Nickel), as

well as symptoms reported to have been experienced by patients with defective hip implants (ATSDR 2004, 2012, 2005, Nordberg *et al* 2007, Casarett & Doull 2019). Moreover, exposure to metal ions and debris from hip implants has been linked to adverse effects in patients that are consistent with Mrs. Rouviere's reported symptoms.

6. It is my opinion that the hip implants exposed Mrs. Rouviere to metal debris and ions released from wear of the implants between 2012 and 2017, and that it is more likely than not that this exposure would increase her risk of experiencing adverse health effects that have been associated with metal debris release (as previously reported in the literature). The symptoms manifested in Mrs. Rouviere are consistent with exposure to toxic metal debris as has been reported in this literature and support my opinion that the metal debris from the hip replacements increased Mrs. Rouviere's risk of experiencing adverse immunological and neurological symptoms, similar to her medical conditions described after her first surgery in 2012.

5. On or about March 27, 2021, I received a final supplemental report and opinion of Dr. Gannon dated March 22, 2021. On reviewing Dr. Gannon's draft supplemental report and opinion, I learned for the first time the results of the examination of tissue specimens of Jodi Rouviere labeled/marked S16-15059, S17-2298 A1, and S17-2298 B1, in which Dr. Gannon states:

**a.** "The slide labeled S16-15059 shows densely collagenized fibrous and fibroadipose tissue with abundant metal-laden macrophages (Fig 1 below)."

**b.** "The slide labeled S17-2298 A1 consists of densely collagenized fibrous and fibrovascular tissue with numerous metal-laden macrophages, tissue necrosis, larger metal particles consistent with titanium debris and lymphocytes (Fig 2 below). Additionally,

granulomas are seen indicating a type 4 hypersensitivity reaction. The larger titanium particles were not a feature of the tissue available in my original report.”

c. “Slide S17-2298 B1 shows bone and bone marrow (Fig 4 below). The bone is severely osteopenic with numerous resorptive surfaces and remodeling. The bone marrow shows trilineage maturation with no atypical features in this material.” And

d. “[T]hese slides show an ongoing and severe adverse reaction to metal debris in Mrs. Rouviere that continues despite revision in her prosthesis. These changes will likely continue as the metal has been shown in this material to stay resident in the body leading to additional pain and suffering.”

e. “Substantial amounts of wear debris from the Cobalt and Chromium (CoCr) from metal hip implants were released into the joint tissue environment of the synovium and surrounding capsule. This wear debris was ingested by macrophages that were present and were recruited to the local environment. The metal wear debris ingestion leads to localized cellular death and significant scarring. This necrosis is directly associated with the metal laden macrophages. These morphologic and physiologic changes led to clinical symptoms and/or findings in this case, which necessitated right hip revision surgery. Mrs. Rouviere experienced an adverse reaction to metal debris as a result of wear from metal-to-metal contact in the implanted hip components. This led to accumulation of metal wear debris in and around the implant site, causing subsequent tissue destruction, bone damage, pain and difficulty ambulating and eventually leading revision surgery.”

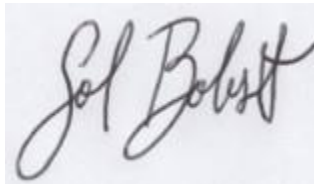
6. Had I been provided the information contained in Dr. Gannon’s supplemental report described in the preceding paragraphs of this declaration, which included Dr. Gannon’s identification of titanium particles, I would have performed additional analyses of the explanted

components including, but not limited to, estimating the total amount of titanium released into Mrs. Rouviere's synovium and surrounding capsule due to metal wear while implanted. Dr. Gannon's supplemental findings and opinions included titanium, as well as cobalt and chromium, wear debris in the list of metals released into Mrs. Rouviere's body that led to tissue destruction, bone damage and pain. Had this information specific to her adverse reactions to titanium wear debris been available to me, I would have focused additional attention to those specific titanium components during my non-destructive evaluation. The results from the additional analyses would have been compared to data available in the published literature.

7. Had I been provided the information contained in Dr. Gannon's supplemental report described previously in this declaration, I would have had additional opinions concerning the source of metal debris that caused the adverse tissue reactions in Mrs. Rouviere and which specific implanted components contributed to the wear debris.

8. Based on the newly produced tissue specimens labeled S16-15059, S17-2298 A1, and S17-2298 B1, and Dr. Gannon's Supplemental Report and Opinion, my original report and opinion dated September 21, 2020, is now rendered incomplete, altered and need of modification for the reasons stated in the preceding paragraphs of this declaration.

PURSUANT TO TITLE 28 U.S.C. 1746, I, Sol Bobst, PhD DABT hereby declare and affirm that the foregoing facts and claims are true and correct, done under penalties of perjury on this 29th day of March 2021.

A handwritten signature in black ink, reading "Sol Bobst", is centered on the page. The signature is written in a cursive, flowing style.

---

Sol Bobst, PhD DABT